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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,502	10/11/2001	Jerry G. Henslee	5972.US.P7	1118

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EXAMINER

HARRIS, ALANA M

ART UNIT	PAPER NUMBER
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1643

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/975,502

Applicant(s)

HENSLEE ET AL.

Examiner

Alana M. Harris, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-4 and 6-8 is/are pending in the application.
- 4a) Of the above claim(s) 6-8 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2-4 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 04, 2005 has been entered.

2. Claims 2-4 and 6-8 are pending.

Claims 6-8, drawn to non-elected inventions are withdrawn from examination.

Claim 2 has been amended.

Claims 2-4 are examined on the merits.

Withdrawn Rejections

Claim Rejections - 35 USC § 112

3. The rejection of claims 2-4 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement have been withdrawn in light of Applicants explicitly pointing out where support can be found in the specification, see "Rejection..." section beginning on page 7 of the Remarks submitted October 13, 2004.

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4. The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the arguments presented on page 7 of the Remarks.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The rejection of claims 2-4 under 35 U.S.C. 103(a) as being unpatentable over United States Patent Application Publication number 2002/0009738 A1 (January 24, 2002) is maintained.

Applicants aver the Patent Application Publication document does not necessarily encode expressed proteins and "there are many polynucleotides which are never translated...", see page 9 of the Remarks. Applicants list how their claimed invention differs from the publication document in that the invention claimed "...relates to the detection of actual polypeptide markers (or complexes thereof) present in specific combinations.", see page 9 of the Remarks, first full paragraph. "Applicants note the claimed invention is quite distinct from the teachings and suggestion of Houghton et al. [the patent application publication]." And in conclusion, Applicants state that MPA, BU101 and BS106 are not disclosed nor suggested in the patent application publication

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document, last paragraph of page 9 of the Remarks. These arguments and points of view have been carefully considered but found unpersuasive.

Applicants' attention is directed to page 8 of the Action mailed April 6, 2004. US patent application publication #2002/0009738 teaches Applicants' BS106 (SEQ ID NO: 8) and BU101 (SEQ ID NO: 6), which are the same as the publication's sequence 31 and sequence 77, respectively. Even though the names and/or acronyms listed for identical sequences are different, nonetheless they are the same proteins. It is clear these amino acid sequences were expressed proteins and translated, see page 4, sections 0055 and 0056 and page 5, sections 0101 and 0102. These molecules are breast tumor proteins that may be detected in diagnostic methods, see abstract.

The publication teaches that diagnosis of cancer can be performed and the change in the level of reactive polypeptide(s) evaluated, see page 9, section 0145. The publication also provides teachings of diagnostic methods, which include a monoclonal antibody or fragment thereof that specifically binds to a breast tumor protein, see page 12, section 0179. A variety of biological samples may be tested for the breast tumor proteins, such as urine, a tumor biopsy sample, or a lymph node, see page 9, section 0139.

The publication does not teach a method of detecting a combination of polypeptides in a test sample with at least two antibodies with the subsequent formation of antigen/antibody complexes of each member of said combination via an immunoassay and resulting in the indication of breast cancer in a patient. However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the

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claimed invention was made to utilize antibodies via an immunoassay in the detection of the taught breast tumor proteins in a patient sample within a tissue section or cell culture. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of the publication to detect two breast tumor proteins because the publication notes that "what is needed in the art is a methodology that employs the detection of two or more breast cancer specific genes in order to improve the sensitivity and reliability of detection of micrometastases, ", see page 1, section 0009. It would follow that the detection of encoded polypeptides would be useful in the diagnosis of breast cancer. Not only does the cited statement provide one of ordinary skill in the art impetus to implement the claimed invention with a reasonable expectation of success. It is clear from this statement in the prior art that an assay of a specific combination of breast tumor markers is contemplated and this detection includes the use of antibodies, see page 1, section 0009; page 9, section 0145; page 12, section 0179; and page 17, section 0209.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (571) 272-0831. The examiner works a flexible schedule, however she can normally be reached between the hours of 7:30 am to 6:30 pm with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ALANA M. HARRIS, PH.D.

PRIMARY EXAMINER

Alana M. Harris
Alana M. Harris, Ph.D.
25 October 2005